

OCT 24 2003

NuVasive®, Inc.

**VII. 510(k) Summary**

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92, the following summary of information is provided:

**A. Submitted by:**

Laetitia Bernard  
Manager of Regulatory Affairs and Quality Assurance  
NuVasive, Incorporated  
10065 Old Grove Road  
San Diego, California 92131  
Telephone: (858) 271-7070  
Telefacsimile: (858) 271-7101

**B. Device Name**

Trade or Proprietary Name: *NuVasive NeuroVision JJB System*  
Common or Usual Name: Electromyography (EMG) monitor/stimulator  
Classification Name: Surgical nerve stimulator/locator  
Device Class: Class II  
Classification: §874.1820, §882.1870  
Product Code: 77ETN, 84GWF

**C. Predicate Devices**

The subject *NeuroVision JJB System* is substantially equivalent to the *NeuroVision JJB System* currently manufactured and distributed commercially in the U.S. by NuVasive.

**D. Device Description**

The *NVJJB System* utilizes conventional neurophysiologic monitoring to reduce the incidence of injury to nerve roots during instrumented spine surgery. In the procedure, stimulus evoked electromyography is used to determine changes in nerves. Corresponding muscle groups are monitored using surface electrodes, while stimulation is used to detect nerve responses.

The NeuroVision JJB System consists of a reusable Patient Module, a Control Unit comprised of an embedded computer with touch screen controls and an interface card, and an assortment of disposable and reusable conductive probes, electrodes, and electrode leads.

**E. Intended Use**

The NeuroVision JJB System is intended to provide stimulation of spinal nerves during surgery of the spine, and intraoperative electromyographic (EMG) nerve surveillance to assist, by administration of brief electrical stimulus pulses to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves, in the following: a) Location and evaluation of spinal nerves, using the System's Screw Test, Detection, and/or Free Run EMG Functions; and b) Location and identification of spinal nerves, using the System's Nerve Retraction Function.

The NeuroVision JJB System is designed for use in conjunction with other NuVasive devices to assist in gaining controlled access to, and visualization of, the spinal nerve root, foramina, intervertebral disc, and surrounding tissues of the spine via uniportal or biportal approach, where anatomical restrictions safely permit.

**F. Comparison to Predicate Devices**

The subject device has indications for use identical to those of its predicate, and employs the same principles of operation. Due to this equivalency, the device raises no new safety or effectiveness issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 24 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Laetitia Bernard  
Manager of Regulatory Affairs  
and Quality Assurance  
Nuvasive, Inc.  
10065 Old Grove Road  
San Diego, California 92131

Re: K032083  
Trade/Device Name: NeuroVision JJB System  
Regulation Number: 21 CFR 874.1820, 890.1375  
Regulation Name: Surgical nerve stimulator/locator  
Diagnostic electromyograph  
Regulatory Class: II  
Product Code: ETN, GWP  
Dated: September 24, 2003  
Received: September 25, 2003

Dear Ms. Bernard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

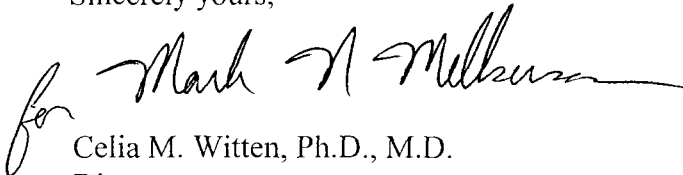
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark A. Melkerson

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

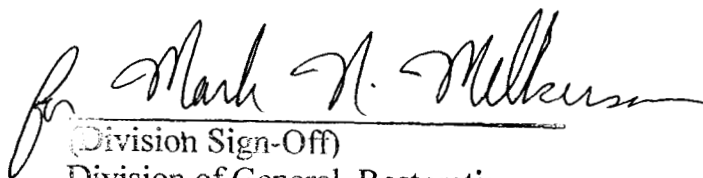
Enclosure

**D. Indications for Use Statement**510(k) Number (if known): K032083Device Name: NeuroVision JJB System

Indications for Use:

The NeuroVision JJB System is intended to provide stimulation of spinal nerves during surgery of the spine, and intraoperative electromyographic (EMG) nerve surveillance to assist, by administration of brief electrical stimulus pulses to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves, in the following: a) Location and evaluation of spinal nerves, using the System's Screw Test, Detection, and/or Free Run EMG Functions; and b) Location and identification of spinal nerves, using the System's Nerve Retraction Function.

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(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K032083

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐